Remarks

The application has been amended. These amendments do not introduce new matter. In particular, paragraph [0003] has been amended to correct a typographical error in the patent number for the patent to Hillstead.

Claim 1 has been amended to positively recite that the first polymeric liner is bonded to the second polymeric layer. Also, claims 9 and 11 have each been amended to change the term "reservoir" to "pocket", proper antecedent basis for which can be found in claim 1. It is noted that the term "pocket" was used interchangeably with the term "reservoir pocket" in the specification (see for example, paragraph [0040]).

Claim Rejections Under 35 U.S.C. §112, Second Paragraph

The Examiner has rejected claims 11-12 under 35 U.S.C. §112, second paragraph as being allegedly indefinite. In particular, the Examiner states that there is insufficient antecedent basis for the term "said reservoir" in claim 11.

These rejections have been addressed in the amendments presented herewith.

Claim Rejections Under 35 U.S.C. §102(e)

The Examiner has rejected claims 11-22 and 27 under 35 U.S.C. §102(e), as allegedly being anticipated by U.S. Patent Application No. 2003/0074049. In particular, the Examiner states the following:

> **Hoganson et al. discloses the claims as currently presented comprising: a first polymeric liner; a second polymeric liner (see 2c for both liners 22); an intermediate structural member (10) interposed between the first and second liners wherein the structural member is defined by solid segments (the struts) and openings (the cells) therebetween, such that the first liner can be bonded [0095] to the second liner through the openings to**

form at least one pocket about the solid segments; and a bioactive agent located within the pocket/cell about the solid segments of the intermediate structural member (this last limitation is met because the second polymeric layer 22 (see figure 2c) is bonded to/through the stent cells (24) to join to the inner or first layer polymeric layer and the drugs are incorporated into the pores of the polymer. Therefore, the bioactive agent is in this pocket/cell (read section [0078], section [0095] that states compress the stent, and section [0105]). See section [0066 for stent details; [0105-0116] for drug/agent details; [0079] for varying the porosity; and [0071-0076] tables 1 and 2 for types of polymers utilized.

After reviewing the Office Action Summary, Applicant believes that the Examiner intended to reject claims 1-22 and 27 here. Therefore, the present rejection will be addressed with respect to these claims. In consideration of the claim amendments and the arguments presented herewith, the rejection of claims 1-22 and 27 is respectfully traversed.

Amended claim 1 provides a device for delivery of bioactive agents associated therewith to a site of implantation of the device. The device includes a first polymeric liner, a second polymeric liner, and an intermediate structural member defined by solid segments and openings therebetween. The first polymeric liner is bonded to the second polymeric liner through the openings so as to form a pocket about the solid segments. The device further includes a bioactive agent located within the pocket.

Hoganson discloses a covered stent. As recognized by the Examiner, in Fig. 2c, an embodiment is shown where a cover is located on the exterior of the stent framework, and a cover is located on the interior of the stent framework. However, contrary to the Examiner's assertions, Hoganson fails to disclose that these stent covers are bonded to each other through stent openings so as to form pockets. The Examiner refers to paragraph [0095] for its alleged teachings with respect to bonding of the covers (polymeric liners). While this paragraph states that "when heated, the polymer tube will radially shrink and compress against the stent", it fails

to disclose a process by which multiple polymeric covers may be bonded to each other through stent openings. While bonding is mentioned in Hoganson, it is only with respect to laminated covers, where the polymer may be bonded to itself or the stent or both [0099]. However, there is no suggestion to bond/laminate polymeric layers to each other through the open portions of an intermediate stent and no disclosure or suggestion of the formation of pockets about the stent, as set forth in the claims.

The Hoganson reference also fails to show a bioactive agent located in a pocket as set forth in the claims. As recognized by the Examiner, the drug particles in Hoganson are incorporated into the material making up the cover [0105]. The Examiner alleges that the bioactive is located in a pocket about the solid stent segments "because the second polymeric layer 22 (see figure 2c) is bonded to/through the stent cells 24 to join to the inner or first polymeric layer and the drugs are incorporated into the pores of the polymer". As already discussed above, Hoganson fails to disclose bonding of the polymeric layers to each other through stent openings to form pockets. Moreover, even if this condition were met, which it is not, it would be impossible for the drug to be in the pores of the cover while at the same time being in spaces between the solid stent portions. Paragraph [0078] of Hoganson states that the cover may be located in the interstitial spaces between portions of sections 24 of the stent framework, so as to effectively be in the "middle" of the stent. However, Applicants submit that this is a general disclosure relating to the relative positioning of the covers within the various stent configurations, and relates neither to Fig. 2c nor to the location of drugs per se. In fact, the only embodiment disclosed which includes polymer between the solid stent portions appears to be the embodiment shown in Fig. 8 and discussed in paragraph [0097], where the covered stent includes a cover on the middle of the stent body without any pockets containing a drug as set forth in the claims.

Since the Hoganson reference fails to disclose or suggest bonding of the polymeric layers through open stent portions to form pockets for containing a bioactive agent, the claims of the present invention are deemed to be patentably distinct over Hoganson.

Claim Rejections Under 35 U.S.C. §103 (a)

The Examiner further rejects claims 23-26 as being allegedly unpatentable over Hoganson, et al. in view of U.S. Patent No. 6,001,125 to Golds, et al. In particular, the Examiner uses the Golds reference for its disclosure with respect to internodal distance.

Claims 23-26 are dependent upon claim 1. As set forth above, claim 1 is patentably distinct over the primary reference. The Golds reference fails to fill the deficiencies of the primary reference. Therefore, claims 23-26 are similarly patentable.

Summary

Applicant has responded in full to the present Office action. It is believed that all of the claims of the present invention are patentable over the cited references, either alone or in combination. Favorable action thereon is respectfully solicited.

Should the Examiner have any questions or comments concerning this Response, the Examiner is respectfully invited to contact the undersigned agent at the telephone number set forth below.

Respectfully submitted,

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